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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,710	08/05/2003	Richard J. Yarwood	03762.012500.3	1897
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Fitzpatrick Cella (Catalent) 1290 Avenue of the Americas New York, NY 10104-3800				
EXAMINER				
SOROUSH, ALI				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/635,710

Applicant(s)

YARWOOD ET AL.

Examiner

ALI SOROUSH

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 06/18/2009 to the Office Action mailed on 03/19/2009 is acknowledged.

Status of the Claims

Claim 24 is currently amended and claims 1-23 and 39 are cancelled. Therefore, claims 24-38 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Double Patenting

1. The rejection of claims 24-38 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 4-16 of U.S. Patent No. 6,726, 928 B2 **is maintained**. Applicant's argument that once all other issues concerning the pending application have been addressed they will then file a terminal disclaimer is acknowledged. The rejection is therefore maintained until the terminal disclaimer is filed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
 2. Determining the scope and contents of the prior art.
 3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. The rejection of claims 24-34, and 37 are rejected under 35 U.S.C. 103(a) as

being unpatentable over Gregory et al. (US 4305502, Published 12/15/1981) in view of Mughal (US 4465838, Published 08/14/1984) **is maintained**.

Applicant Claims

Applicant claims a process for the preparation of a solid, rapidly disintegrating dosage form comprising a pharmaceutically active substance in an aqueous or alcohol solvent and further comprising a carrier materials (i.e. gelatin), rendering the active substance less soluble. The process further comprises the composition being filled into a plurality of mold pockets in a film and frozen, which is further freeze-dried, or vacuum dried to remove the solvent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Gregory et al. teaches, "The invention relates to packages containing shaped articles carrying chemicals, particularly to pharmaceutical dosage forms carrying pharmaceuticals. The shaped articles, which disintegrate rapidly in water are contained

in depressions in sheets of filmic material and are enclosed by a covering sheet adhering to the filmic material." (See abstract). "The shaped articles are prepared by a process which comprises subliming solvent from a composition comprising the chemical (e.g. pharmaceutical substance) and a solution of carrier material in a solvent ..." (See column 3, Lines 21-25). "The carrier material can be any water soluble or water dispersible material that is pharmacologically acceptable or inert to the chemical and which is capable of forming a rapidly disintegratable open matrix network." (See column 2, Lines 53-57). "A particularly advantageous carrier may be formed from polypeptides such as gelatin..." (See column 2, Lines 60-62). "The solvent is preferably water but it may contain a cosolvent (such as alcohol e.g. tert-butyl alcohol) ..." (See column 3, Lines 32-34). Gregory further teaches, "A measured quantity of the composition may be added to each depression and the filmic material containing the filled material then cooled ... When the contents of the depressions are frozen the filmic and contents may be subjected to reduced pressure ...to aid the sublimation." (See column 5, Lines 12-20). "A large sheet of filmic material ... containing numerous depressions may be subjected to the freeze drying procedure and the covering sheet may then be adhered to it." (See column 5, Lines 24-26). In a preferred example Gregory et al. teaches that the active agent is oxaprozin and Lorazepam. (See column 5, example 1 and column 6, example 3). The method of formulation of a pharmaceutically active agent into a readily dissolving, orally administered tablet taught by Gregory et al. has the inherent property of rendering the active substance less soluble and more palatable. Therefore, it would

be expected that an identical process, such as that taught by Gregory et al., would necessarily also render the active substance less soluble and more palatable.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Gregory et al. lacks a teaching of the active substance being presented in a less soluble form prior to formation of said system. Mughal cures this deficiency.

Mughal teaches that oxaprozin has a very bitter taste and teaches a method of forming an insoluble calcium oxaprozin which is less bitter. (See column 1, Line 11 and Lines 28-40).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Gregory et al. with Mughal. One would have been motivated to do so because Mughal teaches the use of this insoluble oxaprozin would provide a tablet that does not have a bitter taste. For the foregoing reasons the instantly claimed process and composition are made obvious.

Response to Applicants Arguments

Applicant argues that Gregory et al. does not teach rendering an active substance less soluble either prior to or while forming a solution or suspension in the presence of a carrier material and that the teaching of Mughal et al. does not cure this

deficiency since it would be counterintuitive for one to combine the teachings of Gregory et al. with Mughal et al. Applicant argues that given Gregory et al.'s preference for readily soluble active ingredients one of ordinary skill in the art would not look to decrease the solubility of the intended active agent. Applicant's argument has been fully considered but found not to be persuasive. Mughal et al. teach that oxaprozin should be formed into calcium oxaprozin which is less soluble in order to reduce the bitter taste prior to tableting. With regard to Applicant's assertion that it would be counterintuitive for one to render the active less soluble given Gregory et al.'s logical preference for soluble active agents, it is the Examiners position that Gregory et al. has not indicate any such preference and that Gregory et al. has examples using both soluble and insoluble active agents (lorazepam). Therefore, one of ordinary skill in the art would expect success in practicing the taught by Gregory et al. with both soluble and insoluble active agents. For the foregoing reasons, the rejection of claims 24-34, and 37 under 35 U.S.C. 103(a) is maintained.

2. The rejection of claims 35 and 38 under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. (US 4305502, Published 12/15/1981) in view of Kurazumi et al. (US 5182112, Published 01/26/1993) **is maintained**.

Applicant Claims

Applicant claims a process for the preparation of a solid, rapidly disintegrating dosage form comprising a pharmaceutically active substance in an aqueous or alcohol solvent and further comprising a carrier materials (i.e. gelatin), rendering the active substance less soluble. The process further comprises the composition being filled into

a plurality of mold pockets in a film and frozen, which is further freeze-dried, or vacuum dried to remove the solvent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Gregory et al. teaches, "The invention relates to packages containing shaped articles carrying chemicals, particularly to pharmaceutical dosage forms carrying pharmaceuticals. The shaped articles, which disintegrate rapidly in water are contained in depressions in sheets of filmic material and are enclosed by a covering sheet adhering to the filmic material." (See abstract). "The shaped articles are prepared by a process which comprises subliming solvent from a composition comprising the chemical (e.g. pharmaceutical substance) and a solution of carrier material in a solvent ..." (See column 3, Lines 21-25). "The carrier material can be any water soluble or water dispersible material that is pharmacologically acceptable or inert to the chemical and which is capable of forming a rapidly disintegratable open matrix network." (See column 2, Lines 53-57). "A particularly advantageous carrier may be formed from polypeptides such as gelatin..." (See column 2, Lines 60-62). "The solvent is preferably water but it may contain a cosolvent (such as alcohol e.g. tert-butyl alcohol) ..." (See column 3, Lines 32-34). Gregory further teaches, "A measured quantity of the composition may be added to each depression and the filmic material containing the filled material then cooled ... When the contents of the depressions are frozen the filmic and contents may be subjected to reduced pressure ...to aid the sublimation." (See column 5, Lines 12-20). "A large sheet of filmic material ... containing numerous depressions may be subjected to the freeze drying procedure and the covering sheet may then be adhered

to it." (See column 5, Lines 2426). The method of formulation of a pharmaceutically active agent into a readily dissolving, orally administrated tablet taught by Gregory et al. has the inherent property of rendering the active substance less soluble and more palatable. Therefore, it would be expected that an identical process, such as that taught by Gregory et al., would necessarily also render the active substance less soluble and more palatable.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Gregory et al. lacks a teaching of the active substance is loperamide. Kurazumi et al. cure this deficiency.

Kurazumi et al. teach formulating an anti-diarrhea composition comprising loperamide hydrochloride, sucrose, and sodium bicarbonate which as added to a carrier composition. (See title and Column 6, example 6, Lines 44-63). Such a composition has the advantage of having an enhance activity and lower side effects. (See column 2, Lines 12-17).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Gregory et al. and Kurazumi et al. One would have been motivated to do this so that the composition of Kurazumi et al. could be formed into a blister pack of tablets for dispensing to a patient. Wherein the advantage of doing so by the process of Gregory et al. would "enable packages of the shaped

articles to be produced in which the handling of the individual shaped articles may be eliminated until the user ... removes the product from the depression in the package immediately prior to use." (See Gregory et al. column 4, Lines 1-6). With regard to the limitation that the active agent be rendered less soluble prior to or at the same time as the formation of the system, it is the Examiners position that this is implicit to the composition of Kurazumi et al. since it includes sodium bicarbonate. The applicant's specification indicates that sodium bicarbonate renders loperamide hydrochloride less soluble. (See specification page 15, example 1). For the foregoing reasons the instantly claimed process and composition are made obvious.

Response to Applicant's Arguments

Applicant argues that one of ordinary skill in the art would not have been motivated to combine the teachings of Gregory et al with Kurazumi et al. Specifically, Applicant argues that the formulation amounts taught by Kurazumi et al. would not be used to arrive at the dosage form taught by Gregory et al. Applicant's arguments have been fully considered but found not to be persuasive. It is the Examiners position that one of ordinary skill in the art would have adjusted the concentrations of the composition taught by Kurazumi et al. through routine optimization to arrive at the dosage form taught by Gregory. For the foregoing reasons, the rejection of claims 35 and 38 under 35 U.S.C. 103(a) is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business

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Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616